

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Jennifer Grudzien et al.

Serial No.: 10/784,092 Filing Date: February 20, 2004
GAU: 1797 Confirmation No.: 6907
Examiner: Natalia A. Levkovich Docket No.: GBL09301CIP
For: REACTION SURFACE ARRAY DIAGNOSTIC APPARATUS

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AMENDED APPEAL BRIEF

Responsive to the Notification of Non-Compliant Appeal Brief mailed October 13, 2009,
Applicants submit herewith an amended Appeal Brief to replace the Appeal Brief filed
July 2, 2009.

Please charge any cost incurred in the filing of this amended Appeal Brief, along with
any other costs, to Deposit Account No. 503397.

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PATENTS, Commissioner for Patents,
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November 13, 2009

Date

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I. REAL PARTY IN INTEREST

The real party in interest is Grace Bio-Labs, Inc.

II. RELATED APPEALS AND INTERFERENCES

Applicants are not aware of any appeals or interferences that may be related to, or directly affect or be directly affected by or have a bearing on, the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1 and 3-10 were previously pending, with all other claims cancelled. An amendment filed November 12, 2009 added the limitations of claims 4 and 6 to claim 1 and further included two terminal disclaimers to reduce issues for appeal. Thus, currently, claims 1, 3, 5, and 7-10 are pending and under appeal.

IV. STATUS OF AMENDMENTS

An amendment filed November 12, 2009 added the limitations of claims 4 and 6 to claim 1 and further included two terminal disclaimers to reduce issues for appeal. Applicants are unaware as to whether the amendment has been entered by the Examiner. Applicants submit that the amendment should be entered as it reduces issues for appeal.

V. SUMMARY OF CLAIMED SUBJECT MATTER

In situ diagnostic techniques have evolved into a high-speed, highly automated process. Standard size test chambers in the form of microarrays of columns and rows of individual wells (i.e., open chambers) are formed by means of a microtitre plate or plates on a substrate to which the microtitre plate(s) is(are) attached. The standard matrix of columns and rows is available in different sizes to suit different automated equipment.

However, the inventors herein recognized that several problems existed in the state of the art. First, it was cumbersome and time consuming to create an array of reaction surfaces from a plurality of microscope slides that maintained the microtitre well spacing across the array. Specifically, the inventors herein recognized that this was particularly problematic when different starting slides were used with different reaction elements in the reaction surfaces. In other words, the different slides were to be tested at the same time and with the same equipment, yet the microtitre spacing across the array had to be maintained.

Complicating the situation, it was often necessary to break down only part of the array in order to perform still further tests and processes on the reaction surfaces. Then, again, the array needed to be reassembled for still further processing.

Finally, the inventors herein also recognized that individual wells required a guaranteed fluidically tight seal to ensure proper reactions and effective automated testing.

Against this backdrop of competing objectives, the inventors herein developed the reaction surface array diagnostic apparatus (shown in FIGS. 3-4, 12-17), comprising:

- a substrate with a plurality of reaction surfaces predeposited in microtiter well spaced bound arrays on the substrate (see elements 102, 104, of FIG. 3, page 9 [0067]-[0070], for example);

- a plate having a plurality of wells extending therethrough in microtiter well spacing (see elements 112 and 116, FIG. 3, page 9 [0071]);

a gasket fluidically sealing the plate to the substrate, the gasket having microtiter well spaced wells combining with the wells in the plate to form reaction chambers about the reaction surfaces on the substrate (see elements 120, 124, 116, 112, 110, FIGS 3-4, including 4D, pages 9-10 [0071]-[0072]); and

a pair of C-shaped clamps engaging opposed edges of the plate and the substrate, the clamps compressing the gasket between the plate and the substrate, wherein each clamp of the pair of clamps comprises two spaced legs extending in the same direction from opposite ends of a central wall, the apparatus further comprising an array of a plurality of side-by-side arranged stacks, each stack individually joined together by the pair of C-shaped clamps, the wells in each stack maintaining a microtiter plate well spacing across the array (see elements 200, 210, 202, 204, 206, 112, 102, FIGS. 12-15, pages 13-14, [0091]-[0092], for example).

As one example embodiment, FIG. 12 shows an example stack formed by the substrate 102, plate 112, gasket 120, and a pair of C-shaped clamps 200. Further, FIGS. 16-17 show how an array of a plurality of side-by-side stacks can be arranged, where each stack is individually joined together by a pair of the C-shaped clamps, and further where the wells maintain a microtitre plate well spacing across the array. In other words, wells from one stack are maintained in microtitre well spacing in relation to wells in another, adjacent, stack.

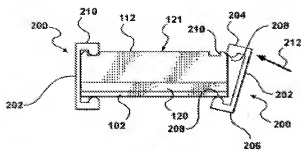


FIG - 12

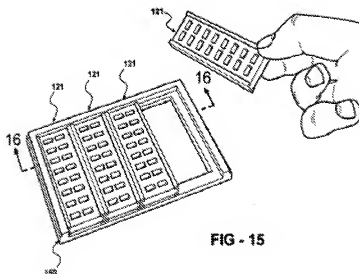


FIG - 15

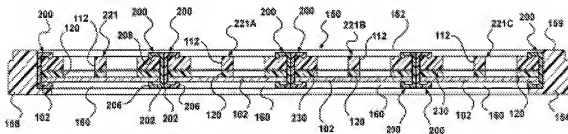


FIG - 16

It is by this unique combination of elements that the above-recognized issues can be addressed. Namely, by using C-shaped clamps with the specified legs and central wall, it is possible to enable easy and quick assembly and disassembly. However, this is just the start. The claimed configuration also enables individually joined stacks, thus providing the ability to

individually disassemble one stack, while remaining stacks are still tightly sealed in order to preserve the reaction state of those stacks. All of this is achieved while also enabling the stacks to be processed together because the array maintains the microtitre well spacing among the stacks. In other words, as shown in FIG. 16, the wells of one stack are in microtitre well spacing with the wells of the adjacent stack, since the C-shaped clamps, when abutted side-by-side, align and position the plates with respect to one another such that the desired spacing across the array is in fact microtitre well spacing. Finally, all of this is achieved while also ensuring that the individually joined stacks form a guaranteed fluid tight seal, even if an adjacent stack is removed and/or disassembled.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

According to the record, the §112 rejections have been withdrawn. Applicants hereby appeal the obviousness rejection of claims 6-10, by rewriting the limitations of claim 6 into claim 1, including the intervening claims. Herein, Applicants will refer to the rewritten claim 6 as “claim 1.”

It should be noted that claims 6-10 were also provisionally rejected under the doctrine of obviousness-type double patenting. However, Applicants’ amendment filed November 12, 2009 included terminal disclaimers to obviate the double patenting issues.

As such, the only remaining rejection of claims 6-10 is under the grounds of obviousness, as summarized below, and thus these issues are under appeal and before the Board. Further, Applicants also appeal the rejection of claim 3, which now also falls under the rejection of amended claim 1.

Specifically, Applicants appeal the following grounds of rejection from the Office action mailed July 9, 2008:

Claims 6-10 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hudson et al. (U.S. Patent No. 5,591,646) in view of McGrath et al. (U.S. Patent No. 5,192,503), and further in view of Juncosa et al. (U.S. Patent No. 6,225,109).

Claim 3 is rejected under 35 U.S.C. §102(b) as anticipated by Hudson et al. (U.S. Patent No. 5,591,646).

VII. ARGUMENT

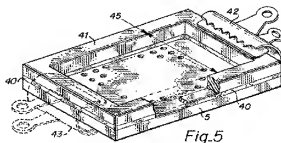
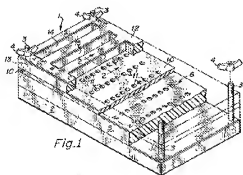
A. Claim 1 is not properly rejected under 35 U.S.C. §103(a)

1. Introduction

Before analyzing the errors in the standing rejection, Applicants believe it will be helpful to first review, in section A.2, the cited references to understand their explicit disclosures. From this, it will then be clear that, even if all three references are combined and modified as suggested, claimed elements are still missing, as shown in sections A.3 and A.5. Section A.4 illustrates that it is improper to combine and modify the references as suggested, as such actions destroy the intended functionality of the multiple references.

2. Review of the cited references

Hudson et al. The Office action first relies on Hudson et al. As shown in FIG. 1 below, Hudson shows a clamped apparatus that purportedly forms an array with a plurality of wells that are all joined together as a complete unit via the screw clamps (3,4). Further, a second, separate embodiment of a border frame with a totally different structure that uses clamps 42, 43 is shown in FIG. 5 below. It should be noted that the device of FIG. 5 does not show any wells formed similar to FIG. 1, but instead includes a single central well 45. Further, it appears from Cols. 9 and 10 that the assembly of FIG. 5 is separate and distinct from that of FIG. 1.



McGrath et al. The Office action then turns to McGrath. Similar to FIG. 1 of Hudson et al., McGrath et al. also relies on screw clamps 166 to create reaction chambers, as shown in FIG. 3 of McGrath reproduced below. However, it should first be noted that McGrath forms only sealed chambers, not wells, as shown in FIG. 8 of McGrath. Second, it should be noted that

McGrath relies on the clamping force of the screw clamps 166, which only guide the slides with the I-shaped beams 144. Specifically, it is clear from the figures and text that McGrath does not generate, and could not generate, any clamping action via the I-shaped beams 144. Third, it is clear from McGrath that all of the four reaction chambers are sealed as a unit – either all of them are sealed, or none of them are sealed. This is clear from FIGS. 3 and 5, reproduced below, which show how the screws 166 clamp down the probe clip 10 and the slide 50 together to form a reaction chamber assembly. Clearly, from FIGS. 3 and 5, the I-shaped structure 144 does not individually clamp the different reaction chambers formed from the probe clips 10 and slides 50.

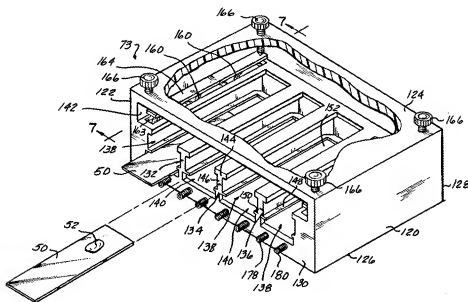


FIG-3

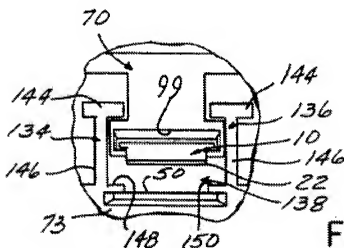


FIG-5

Juncosa et al. The Office action finally relies on Juncosa et al. As shown in FIG. 14 below, Juncosa et al. shows an un-clamped apparatus that forms an array from a plurality of slides 104 and cover plates 106. Specifically, Juncosa et al. explicitly relies on the tray 102 having recesses 105 in the tray 102 separated by wall members 107 to hold the slides 104 and cover plates 106.

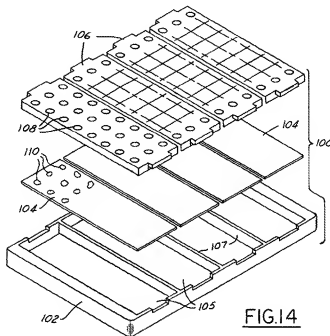


FIG.14

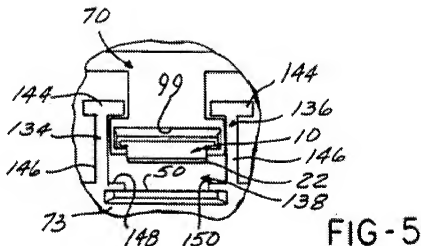
3. *Even if all three references are combined, the combination fails to show an array of a plurality of side-by-side arranged stacks, each stack individually joined together by a pair of the C-shaped clamps.*

As described above, claim 1 requires an array of a plurality of side-by-side arranged stacks, each stack individually joined together by a pair of the C-shaped clamps. The standing rejection relies on McGrath et al. to show this feature. Specifically, the Office action of July 9, 2008 states at page 6:

McGrath discloses, as shown in Figures 1- 7, a system of co-planar stacked slides arranged on a bottom tray 126, each stack being individually joined by clamps (Abstract; Col.10, lines 60 plus).

Applicants disagree. McGrath is in fact incapable of individually joining each stack, by clamps

or any other means. Specifically, as noted above, FIG. 5 of McGrath illustrates how the members 144, 148, 148, and 73 do not clamp/join the upper slide 10 to the lower slide 50 to form the reaction chamber. Rather, they merely guide the upper assembly vertically, so that the screws 166 are able to generate the clamping force. Thus, as illustrated by FIGS. 3-4, it is only once the entire upper assembly is clamped down on the entire lower assembly that all four reaction chambers are formed and sealed. Before clamping, the upper part 70 merely holds the upper slide 10 by engaging only the slide (nothing is clamped via part 70, part 70 only touches the bottom slide member 12). Further, the bottom tray 73 merely holds the bottom slide 50.



As such, McGrath cannot individually join each stack with its disclosed screw clamps 166, but rather joins either all four stacks, or none of the stacks, via clamps.

The Office action appears to take the following statement in the Abstract (that uses the term “individual”) out of context:

Clamps
urge the probe clip cassette and the individual plates
into engagement with the slides to form the sealed
chambers therebetween.

This sentence does not state that each stack is individually joined by clamps – rather, it states that the clamps urge the cassette (containing four individual plates) into engagement with the slides to form four sealed chambers. While subtle, this is an important distinction. The specification and figures make it abundantly clear that the slides are not joined individually via respective clamps. Applicants submit that it would be contrary to the language of the Abstract, and

contrary to the entire specification, to read the above sentence in the Abstract as suggested by the Office action.

The standing rejection relies explicitly on McGrath to show individually joining stacks by clamps. Since McGrath clearly fails to show this feature, and in fact is incapable of showing this feature, the rejection should be reversed for this reason alone.

4. The combination should not be made as it destroys the intended function/purpose of Hudson and/or McGrath.

The standing rejection sets forth the following reasoning in combining the three cited references:

With respect to claims 6-7, 9 and 17-18, Hudson does not teach forming an array of co-planar substrate-gasket-plate stacks joined by clamps such that the array would have a foot print of a micro-titer plate.

McGrath discloses, as shown in Figures 1- 7, a system of co-planar stacked slides arranged on a bottom tray 126, each stack being individually joined by clamps (Abstract; Col.10, lines 60 plus).

Juncosa discloses a co-planar array of assay devices comprising stacked slides (illustrated in Figures 13-14). "A plurality of synthesis devices can be positioned in a support base ['tray' – Ex.] in order to allow sampling in an automated manner. The synthesis devices can be provided in a 96 well microtiter format" (Abstract). It would have been within the ordinary skill of an artisan at the time the invention was made to have arranged the diagnostic devices of Hudson in a similar manner, that is, in a tray supported co-planar array having micro-titer plate format, in order to increase productivity of the diagnostic apparatus and to allow sample handling at a higher automation level.

Applicants now address the addition of McGrath to Hudson, for the alleged purpose of increasing productivity of the apparatus and allowing sample handling at a higher automation level. As noted above, Hudson purportedly provides a plurality of wells. Such wells are required for certain processing, where various solutions are automatically added to the wells.

However, as also noted above, McGrath forms a sealed chamber (i.e., no well) so that the device can be manipulated and turned upside-down, for example, to maneuver materials within the sealed chamber (for example, see FIG. 8 in McGrath). Thus, these two references are fundamentally at odds with one another.

If the coplanar allegedly clamped structure of McGrath formed by a top and bottom plate were applied to Hudson, the fundamental functionality of Hudson would be destroyed. Namely, Hudson relies on the open nature of the wells to achieve the intended purpose of receiving multiple products and washings (see Col. 8, for example). Alternatively, if one tried to apply the well structure of Hudson to McGrath, again the functionality of McGrath would be destroyed since the sample materials would spill out of the well, or not otherwise be contained as required. Clearly, these problems are strong motivation not to combine the references as urged by the standing rejection.

Second, with regard to Juncosa, the standing rejection completely ignores the structural problems that would be encountered in trying to use Juncosa's array with either Hudson or McGrath. For example, assuming McGrath did show individual clamping of each stack, such an approach would be incompatible with Juncosa's tray (shown above in FIG. 14), as there is no disclosed way for individual clamps to work along with the closed bottom recesses 105, and wall members 107 of tray 102.

For these additional reasons, the rejection should be reversed.

5. *Even if all three references are combined, the combination fails to show a pair of C-shaped clamps engaging opposed edges of the plate and the substrate.*

Regarding the addition of Juncosa to McGrath and Hudson, Applicants respectfully submit that if one did use the structure of Juncosa, then claimed elements are necessarily absent. Specifically, claim 1 requires that a pair of C-shaped clamps engage opposed edges of the plate and the substrate. However, Juncosa's FIGS. 13-14 rely on a tray 102 that has closed bottom recesses 105 with particular side walls 107 and tabs to retain the cover plate 106. As such, even if one applied the clamps of Hudson (even clamps 42, 43), or McGrath, the clamps would be physically *unable* to engage opposed edges of the plate and the substrate, since the bottom of the clamp would necessarily need to engage the bottom of the tray. As such, even if combined, the references would necessarily show something different from the apparatus of claim 1.

Further, Applicants respectfully submit that it would be improper to take away the tray of Juncosa, as this tray is fundamentally necessary for Juncosa to achieve its intended purpose and functionality of well spacing across the plurality of stacks.

As such, this is yet another reason why the rejection should be reversed

6. There is no properly cited motivation to combine the references that is supported by evidence of record.

Applicants respectfully submit that the alleged motivation to combine the three cited references is not supported by evidence of record, nor does the alleged motivation explain how one skilled in the art would reach the configuration of claim 1 from the cited references.

Specifically, Applicants fail to understand why one skilled in the art would think that adding the non-individually-clamped sealed reaction chamber of McGrath to the system of Hudson would provide any advantage whatsoever, let alone the advantage of improving automatic processing. The Office action fails to give a reasoned explanation that explains why someone skilled in the art would look to the particular structure of McGrath and find any reason at all to combine it as alleged with Hudson. Applicants find no evidence in the record or any reasoned explanation as to why such a combination would be beneficial for increasing productivity of the apparatus and allowing sample handling at a higher automation level.

Further, Applicants submit that it is improper to pick and choose the otherwise isolated features of the various references when there is no teaching in any reference of record that there is any reason whatsoever to follow such an approach. Only Applicants have recognized and described the advantages of individually joined stacks that maintain microtitre well spacing across the stacks. As such, the only reasonable conclusion is that the standing rejection has used Applicant's claims as a roadmap to pick and choose features of the art and combine them in a specific way that leads to Applicants' invention. Such is not proper.

7. Conclusion

In summary, the configuration of claim 1 achieves numerous advantages simultaneously, making it more than the sum of its parts. It is improper to pick and choose isolated elements from the three references, where clearly none of the cited references point toward the specific and unique combination of claim 1. Only Applicants have recognized the unique advantages of

having individually joined stacks that can be individually formed and sealed, but yet that can also be combined and recombined together to form a larger array that retains microtitre well spacing across the array. Hudson and McGrath cannot achieve these advantages, as they each have only one jointly sealed system. Likewise, Juncosa can't achieve these advantages, as Juncosa relies on the tray to form the sealed stack, with no clamps whatsoever, and no way to apply the clamps as set forth in claim 1.

B. Claim 3 is not properly rejected under 35 U.S.C. §102(b)

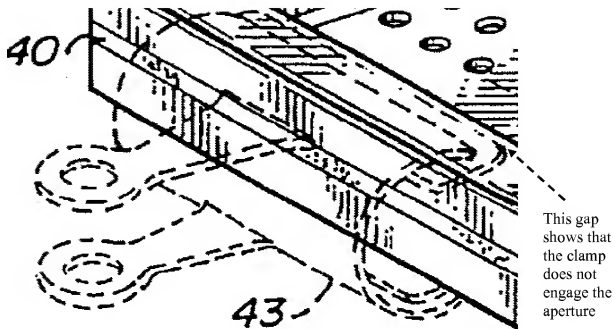
Claim 3 further specifies that there is at least one open ended aperture formed in the plate, and that a projection extending from at least one of the clamps releasably engages with the at least one aperture to releasably fix the clamp to the plate.

The standing rejection relies on Hudson to reject claim 3 and asserts the following:

Figure 5 also shows opposed

C-shaped clamps 42, 43 having a central wall, legs and teeth shaped extending projections (not indexed) "releasably engagable " with an open ended aperture / recess 45 formed in the plate by ridge 41.

Applicants disagree. Even forgetting that the structure of FIG. 5 is fundamentally different from that of FIG. 1 of Hudson, the clamps 42 and 43 are not shown engaging with the aperture 45. Rather, it appears that the clamps stop short of the aperture, and thus do not engage it. This is illustrated in FIG. 5 of Hudson reproduced below, and enlarged with annotations:



This is in contrast to Applicants' approach, in which the clamps do engage an aperture as illustrated in FIG. 12 of Applicants' specification, for example.

For this reason alone, the rejection of claim 3 should be reversed as the cited reference does not show that which is claimed.

C. Claim 9 is not properly rejected under 35 U.S.C. §103(a)

Claim 9 further specifies that two adjacent clamp members of two side-by-side disposed stacks have abutting central walls. Such an approach is shown in FIGS. 15-16 of the present application, for example. Such a configuration achieves the advantage that individually joined stacks can be placed together in a specified way to ensure proper microtitre well spacing across the array of stacks.

Turning to the cited references, it should be clear that the clamps 42 and 43 of Hudson, if arranged to abut an adjacent clamp of an adjacent stack, would destroy any microtitre well spacing across the array of stacks, and thus for this reason alone the rejection should be reversed.

Further, even if all three references are combined, Applicants fail to find any disclosed structure in which two adjacent clamp members of two side-by-side disposed stacks have

abutting central walls. The standing rejection cites to no evidence in the record to support such a rejection and for this additional reason the rejection of claim 9 should be reversed.

D. Conclusion and request for relief

As described in detail above, the standing rejections are inadequate for numerous reasons. Applicants therefore respectfully request that the Board reverse the standing rejections (or any subset thereof if not all rejections can be reversed), and direct the Examiner to allow all pending claims, or any allowable subset thereof.

VIII. CLAIMS APPENDIX

1. (Previously presented) A reaction surface array diagnostic apparatus comprising:
 - a substrate with a plurality of reaction surfaces predeposited in microtiter well spaced bound arrays on the substrate;
 - a plate having a plurality of wells extending therethrough in microtiter well spacing;
 - a gasket fluidically sealing the plate to the substrate, the gasket having microtiter well spaced wells combining with the wells in the plate to form reaction chambers about the reaction surfaces on the substrate; and
 - a pair of C-shaped clamps engaging opposed edges of the plate and the substrate, the clamps compressing the gasket between the plate and the substrate, wherein each clamp of the pair of clamps comprises two spaced legs extending in the same direction from opposite ends of a central wall, the apparatus further comprising an array of a plurality of side-by-side arranged stacks, each stack individually joined together by the pair of C-shaped clamps, the wells in each stack maintaining a microtiter plate well spacing across the array.
2. (Cancelled)
3. (Previously presented) The apparatus of claim 1 further comprising:
 - at least one open ended aperture formed in the plate; and
 - a projection extending from at least one of the clamps and releasably engagable with the at least one aperture to releasably fix the clamp to the plate.
4. (Cancelled)

5. (Previously presented) The apparatus of claim 1 wherein:
the legs and the central wall define a channel for receiving a stack arrangement of the substrate, the gasket and the plate.
6. (Cancelled)
7. (Previously presented) The apparatus of claim 1 further comprising:
a tray having an opening for receiving and supporting the array.
8. (Original) The apparatus of claim 7 further comprising:
a sloped surface formed along one edge of the tray for guiding the array into the tray.
9. (Previously presented) The apparatus of claim 1 wherein:
two adjacent clamp members of two side-by-side disposed stacks have abutting central walls.
10. (Original) The apparatus of claim 1 further comprising:
a non-releasable adhesive fixedly joining the gasket to the plate.

IX. EVIDENCE APPENDIX

None.

X. RELATED APPEAL APPENDIX

None.